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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/065,280

09/30/2002

Jeffrey C. Leung

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ANGIOTECH

P. O. BOX 2840

NORTH BEND, WA 98045

EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

NOTIFICATION DATE

DELIVERY MODE

01/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

angiotechpatents@angio.com

nhart@angio.com

Office Action Summary	Application No. 10/065,280	Applicant(s) LEUNG ET AL.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-9,12-20,22,31-38,51-62,69,70 and 77-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-9,12-20,22,31-38,51-62,69,70 and 77-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2009 has been entered.
2. Claims 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70, and 77-82 are currently pending.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70, and 77-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (US 5,931,855) in view of Morency et al. (US 2003/0149447, hereinafter "Morency"). Regarding claims 1-3, 12-15, 31-38, Buncke discloses the invention substantially as claimed including a barbed suture (Figures 9-11) comprising an elongate body having a first end and a second end and a plurality of barbs (16) projecting from the body. The barbs are arranged in a multiple spiral disposition wherein the barbs are spaced longitudinally along the body such that a plane perpendicular to the longitudinal axis of the suture and cutting transversely

Art Unit: 3734

through the suture and intersecting a barb will not intersect any other barb (Figures 9-11; col 4, ln 58-59; col 9, ln 5-8). In a first barb portion (55a) all of the barbs are only facing toward a first end of the elongate body and in a second barb portion (55b) all of the barbs are only facing toward a second end of the elongate body (col 6, ln 60-67).

The suture may be made of a non-absorbable material including polyester or made of a bio-absorbable material including polylactide or polyglycolide (col 1, ln 20-23).

However, Buncke does not disclose an arcuate base at the underside of the barbs. Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing (¶0040; Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.

Regarding claims 6-9, 16-20, 22, 51-62, 69, 70, and 77-82, Buncke does not disclose does not disclose the specific dimensions of the spirality angle, the barb cut angle, the ratio of the barb cut depth to the suture diameter, the ratio of the barb cut length to the suture diameter, or the ratio of the barb cut distance to the suture diameter. Applicant has not disclosed that having a spirality angle of 12-18 degrees, a barb cut angle of 140-175 degrees, a ratio of barb cut depth to suture diameter of 0.05-0.6, a ratio of barb cut length to suture diameter of 0.2-2, or a ratio of barb cut distance to suture diameter of 0.1-6 solves any stated problem or is for any particular purpose.

Art Unit: 3734

Moreover it appears that the barbed suture of the combination of Buncke and Morency, or applicant's invention, would perform equally well with the suture having any appropriate dimension. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the combination of Buncke and Morency such that the suture had a spirality angle of 12-18 degrees, a barb cut angle of 140-175 degrees, a ratio of barb cut depth to suture diameter of 0.05-0.6, a ratio of barb cut length to suture diameter of 0.2-2, and a ratio of barb cut distance to suture diameter of 0.1-6 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the combination of Buncke and Morency. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Buncke and Morency to incorporate the above parameters since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or the an optimum value involves only routine skill in the art (see *In re Aller*, 105 USPQ 233, *In re Boesch*, 617 F.2d 272, 205 USPQ 215, and MPEP 2144.05).

Additionally, Buncke does not disclose the suture is twisted 2 to 17 times per inch to form the multiple spiral disposition. However, the claim language regarding twisting the suture 2 to 17 times per inch is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection

Art Unit: 3734

may be made and the burden shifted to the applicant to show an unobvious *structural* difference in the product. The Examiner contends the combination of Buncke and Morency discloses a suture having barbs in a multiple spiral disposition (Figures 9-11).

Double Patenting

5. Claims 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70, and 77-82 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36, 58, 60, and 102-140 of copending Application No. 10/065,279, as amended November 19, 2009, in view of Buncke (US 5,931,855). The copending application and the instant application claim common subject matter including a barbed suture comprising barbs with a configuration that includes an arcuate base at the underside of the barbs, wherein the barbs have a multiple spiral disposition on the elongate body. However, the copending application does not specifically recite the multiple spiral disposition includes barbs spaced longitudinally along the body such that a plane perpendicular to the longitudinal axis of the suture and cutting transversely through the suture and intersecting a barb will not intersect any other barb. Buncke discloses a similar barbed suture with a multiple spiral disposition and teaches the barbs are spaced along the suture body such that a plane perpendicular to the suture will only intersect one barb (Figures 9-11; col 4, ln 58-59; col 9, ln 5-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the copending application claims such that they recited the barbs are spaced longitudinally along the body such that the perpendicular plane defined

Art Unit: 3734

above will only intersect one barb. Such a modification would improve the strength of the suture by providing a maximum of one weakened area (i.e. cutting into the suture to form the barb) at each cross section of the suture.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

6. Applicant's arguments, see amendment, filed September 28, 2009, with respect to the rejection(s) of claim(s) 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70, and 77-82 under Buncke (US 5,931,855) and McKenzie (GB 1,091,282) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Morency (US 2003/0149447).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure includes: Ruff (US 5,342,376) and Alcamo (US 3,123,077). Ruff discloses a barbed suture with a multiple spiral disposition wherein the base at the underside of the barbs is arcuate (Figure 3). Alcamo discloses a barbed suture with curved edges (col 2, ll 4-11), and thus a curved underside of the barb.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

Art Unit: 3734

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
January 12, 2010

/K. M. D./
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734